

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|-----------------|----------------|----------------------|---------------------|------------------|--|
| 10/790,562      | 03/01/2004     | Abraham Bout         | 2578-4038.3US       | 9903             |  |
| 24247 7:        | 11/03/2005     |                      | EXAM                | INER             |  |
| TRASK BRITT     |                |                      | SCHLAPKOHL, WALTER  |                  |  |
| P.O. BOX 2550   | )              |                      |                     |                  |  |
| SALT LAKE C     | CITY, UT 84110 | ART UNIT             | PAPER NUMBER        |                  |  |
|                 |                |                      | 1636                |                  |  |

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| <del></del>                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                      | Applicati                                                                                                 | on No.                                                                        | Applicant(s)                                                                                    |             |  |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------|--|--|--|
| Office Action Summary                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                      | 10/790,50                                                                                                 | 62                                                                            | BOUT ET AL.                                                                                     |             |  |  |  |
|                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                      | Examine                                                                                                   | •                                                                             | Art Unit                                                                                        | 11.4.1      |  |  |  |
|                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                      | Walter Sc                                                                                                 | hlapkohl                                                                      | 1636                                                                                            | mes         |  |  |  |
| Period fo                                                                                                                                                                       | The MAILING DATE of this communicati<br>r Reply                                                                                                                                                                                                                                                                                                                                                                      | on appears on the                                                                                         | e cover sheet w                                                               | ith the correspondence a                                                                        | ddress      |  |  |  |
| WHIC<br>- Exter<br>after<br>- If NO<br>- Failu<br>Any r                                                                                                                         | CRTENED STATUTORY PERIOD FOR HEVER IS LONGER, FROM THE MAIL sisons of time may be available under the provisions of 37 SIX (6) MONTHS from the mailing date of this communica period for reply is specified above, the maximum statutory to to reply within the set or extended period for reply will, be eply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b). | NG DATE OF TH<br>CFR 1.136(a). In no ev<br>tion.<br>y period will apply and w<br>y statute, cause the app | HIS COMMUNI ent, however, may a ill expire SIX (6) MON elication to become Al | CATION. reply be timely filed NTHS from the mailing date of this of BANDONED (35 U.S.C. § 133). |             |  |  |  |
| Status                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| 1) 又                                                                                                                                                                            | Responsive to communication(s) filed or                                                                                                                                                                                                                                                                                                                                                                              | n 01 March 2004                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| ,                                                                                                                                                                               | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.                                                                                                                                                                                                                                                                                                                                                         |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| <i>'</i> —                                                                                                                                                                      | Since this application is in condition for a                                                                                                                                                                                                                                                                                                                                                                         | <del></del>                                                                                               |                                                                               | ters, prosecution as to th                                                                      | e merits is |  |  |  |
| ,                                                                                                                                                                               | closed in accordance with the practice u                                                                                                                                                                                                                                                                                                                                                                             | nder <i>Ex parte Qi</i>                                                                                   | <i>layle</i> , 1935 C.E                                                       | ). 11, 453 O.G. 213.                                                                            |             |  |  |  |
| Dispositi                                                                                                                                                                       | on of Claims                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| 4) 又                                                                                                                                                                            | Claim(s) 1-21 is/are pending in the appli                                                                                                                                                                                                                                                                                                                                                                            | cation.                                                                                                   |                                                                               |                                                                                                 |             |  |  |  |
| =                                                                                                                                                                               | 4a) Of the above claim(s) is/are withdrawn from consideration.                                                                                                                                                                                                                                                                                                                                                       |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
|                                                                                                                                                                                 | 5) Claim(s) is/are allowed.                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| •                                                                                                                                                                               | Claim(s) is/are rejected.                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| ·                                                                                                                                                                               | Claim(s) is/are objected to.                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| ,                                                                                                                                                                               | Claim(s) 1-21 are subject to restriction a                                                                                                                                                                                                                                                                                                                                                                           | nd/or election re                                                                                         | quirement.                                                                    | •                                                                                               |             |  |  |  |
| Applicati                                                                                                                                                                       | on Papers                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
|                                                                                                                                                                                 | •                                                                                                                                                                                                                                                                                                                                                                                                                    | raminer                                                                                                   |                                                                               |                                                                                                 |             |  |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.                                        |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| 10)                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                      | •                                                                                                         | •                                                                             | •                                                                                               |             |  |  |  |
|                                                                                                                                                                                 | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).                                                                                                                                                                                    |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| ,—                                                                                                                                                                              | inder 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| •                                                                                                                                                                               | •                                                                                                                                                                                                                                                                                                                                                                                                                    | iorojan priority un                                                                                       | dor 25 II S.C.                                                                | S 110(a) (d) or (f)                                                                             |             |  |  |  |
| -                                                                                                                                                                               | Acknowledgment is made of a claim for f                                                                                                                                                                                                                                                                                                                                                                              | oreign priority un                                                                                        | ider 35 U.S.C.                                                                | § 119(a)-(u) of (i).                                                                            |             |  |  |  |
| a)(                                                                                                                                                                             | ☐ All b)☐ Some * c)☐ None of:                                                                                                                                                                                                                                                                                                                                                                                        | umanta haya har                                                                                           | on received                                                                   |                                                                                                 |             |  |  |  |
|                                                                                                                                                                                 | <ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul>                                                                                                                                                                                                                                    |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
|                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 | ol Stage    |  |  |  |
|                                                                                                                                                                                 | 3. Copies of the certified copies of the application from the International                                                                                                                                                                                                                                                                                                                                          |                                                                                                           |                                                                               | received in this ivationa                                                                       | ii Stage    |  |  |  |
| * 0                                                                                                                                                                             | See the attached detailed Office action fo                                                                                                                                                                                                                                                                                                                                                                           | •                                                                                                         |                                                                               | received                                                                                        |             |  |  |  |
|                                                                                                                                                                                 | see the attached detailed Office action to                                                                                                                                                                                                                                                                                                                                                                           | i a list of the cert                                                                                      | med copies not                                                                | received.                                                                                       |             |  |  |  |
|                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| Attachmen                                                                                                                                                                       | t(s)                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  5) Notice of Informal Patent Application (PTO-152) |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |
|                                                                                                                                                                                 | nation Disclosure Statement(s) (PTO-1449 or PTO<br>r No(s)/Mail Date                                                                                                                                                                                                                                                                                                                                                 | (8UUB)                                                                                                    | 6) Other:                                                                     |                                                                                                 | 102,        |  |  |  |
| S Patent and T                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                           |                                                                               |                                                                                                 |             |  |  |  |

## - DETAILED ACTION

Page 2

Receipt is acknowledged of the papers filed on 3/1/2004.

Claims 1-21 are pending and subject to the following restriction requirement.

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to a cell expressing a proteinaceous substance, classified in class 435, subclass 325.
- II. Claim 21, drawn to a method for producing a proteinaceous substance, classified in class 435, subclass 70.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process, such as to support the replication of adenoviruses.

Page 3

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 10/790,562

Art Unit: 1636

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104.

Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with

an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re

Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86

(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims.

Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

A proteinaceous substance, e.g. choose from claims 10,
 11, 14 and 15.

If Applicant elects a viral protein other than an adenoviral protein in 1, above, a secondary election must be made from the following:

1. A viral protein, e.g. choose from claim 16.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP \$ 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or

identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

## Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application

Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at

Application/Control Number: 10/790,562

Art Unit: 1636

this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D. Patent Examiner Art Unit 1636

October 22, 2005

Tem A Makelya TERRY MCKELVEY PRIMARY EXAMINER

Page 9